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CONFIRMATION NO. ATTORNEY DOCKET NO. FIRST NAMED INVENTOR APPLICATION NO. FILING DATE 10/15/2001 Piero Del Soldato 108907-00021 5185 09/926,327 EXAMINER 04/30/2004 4372 7590 ARENT FOX KINTNER PLOTKIN & KAHN BADIO, BARBARA P 1050 CONNECTICUT AVENUE, N.W. PAPER NUMBER ART UNIT SUITE 400 WASHINGTON, DC 20036 1616 DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	09/926,327	SOLDATO, PIERO DEL
	Examiner	Art Unit
	Barbara P. Badio, Ph.D.	1616
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		
1) Responsive to communication(s) filed on		
2a) This action is FINAL . 2b) This action is non-final.		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is		
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4) Claim(s) 1-12 is/are pending in the application.		
4a) Of the above claim(s) 3,5 and 6 is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6)⊠ Claim(s) <u>11</u> is/are rejected.		
7)⊠ Claim(s) <u>1,2,4,7-10 and 12</u> is/are objected to.		
8) Claim(s) are subject to restriction and/or election requirement.		
Application Papers		
9)☐ The specification is objected to by the Examiner.		
10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).		
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Priority under 35 U.S.C. § 119	. •	
12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).		
a)⊠ All b)☐ Some * c)☐ None of:		
 Certified copies of the priority documents have been received. 		
2. Certified copies of the priority documents have been received in Application No		
3. Copies of the certified copies of the priority documents have been received in this National Stage		
application from the International Bureau (PCT Rule 17.2(a)).		
* See the attached detailed Office action for a list of the certified copies not received.		
Attachment(s)		
1) Notice of References Cited (PTO-892)	4) Interview Summary	
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	Paper No(s)/Mail Da 5) Notice of Informal P	ate Patent Application (PTO-152)
Paper No(s)/Mail Date <u>12/05/01</u> .	6) Other:	

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First Office Action on the Merits

Election/Restrictions

1. Applicant's election of Group I in Paper dated April 01, 1004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Specification

- 2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.
- 3. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

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Claim Rejections - 35 USC § 112

4. Claim 11 provides for the use of the compounds for the preparation of drugs for a specific use, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 11 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Allowable Subject Matter

5. Claims 1, 2, 4, 7-10 and 12 are objected to as containing nonelected subject matter. Claims limited to the elected subject matter, i.e., limited to compounds of Examples 1 and 2 of the present specification, would appear to be allowable over the prior art.

Telephone Inquiry

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:00am-3:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Barbara P. Badio, Ph.D.

Primary Examiner

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BB April 28, 2004